

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Monday, March 9, 2009, 1:00 pm – 2:00 pm ET

Call Summary

I. Welcome and Introductions

In order to improve call management, calls will begin promptly at 1:00 pm ET. Roll call will be conducted by sending an email to Marcia Howard (mhoward@chpa-info.org) to indicate that your participation. After all agenda items have been addressed, anyone who joined late can be de-briefed about the prior discussion. Also, time will be allocated for each discussion topics in hopes of making the calls more efficient and ending a few minutes early so attendees can prepare for the next call or meeting.

Sub-team members are asked to share ideas about how to improve the teleconference process.


II. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or if you are listed and were not on the call) should contact Marcia.

 Virginia Hogan, Teva Pharmaceuticals, USA

 Juris Lazdins, Novartis Consumer Health, Inc.

 Carolyn Lindsay, Cardinal Health

 John Lorenc, Reed Technology and Information Services, Inc.

 Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team co-leader)







 Kathryn Moreng, Bayer Consumer HealthCare

 Jeff Poisson, i4i

 Janet Riffitts, McNeil Consumer Healthcare

 Nick Romano, Novartis Consumer Healthcare

 Howard Shatz, Data Conversion Laboratories, Inc.

-  Barbara Spallitta, Reckitt Benckiser, Inc.
-  Siobhan Stevens-Miles, Merck & Co., Inc.
-  Craig Trautman, Intagras
-  Ranga Velagaleti, BASF Corporation
-  Mark Vranich, Blistex, Inc.
-  Marcia Howard, CHPA staff (sub-team liaison)

III. Next Standing Teleconference: March 23, 2009, 1:00 – 2:00 pm ET (unless cancelled)

Please send any agenda topics to sub-team leaders Paula Markert (GSK), Devon Morgan (Perrigo), and sub-team liaison Marcia Howard (CHPA) at your convenience.

IV. Implementation Date of June 1, 2009

During the February 23rd call, there was a discussion about whether or not the June 1, 2009, implementation date is established by regulations and/or statute. The June 1, 2009, date reflects the agency's use of discretionary enforcement. The law actually required electronic submissions beginning in September 2007 so FDA could have started enforcement at that time. **Therefore, companies should be prepared to be in compliance by June 1, 2009.**

FDA will accept paper submissions that are *postmarked* by May 31, 2009. However, any paper submissions received after this date will likely be returned with information about how to complete electronic submissions via SPL.

V. SPL Submission of the Principle Display Panel (PDP) Information

For OTC product SPL submissions, companies will need to send a jpg file of the flattened carton and provide the text from the PDP as a separate field in the submission. The text information is needed to allow FDA to search for key words

and to view promotional information, claims, etc. that might want to be of interest to FDA.

VI. Development of General SPL Press Release

The SPL Leadership Team (LT) is developing a general press release on SPL to promote and inform affected industries about electronic registration. SPL OTC sub-team members should send suggestions for appropriate organizations and groups (like trade associations, RAPS, DIA), trade/industry publications, etc., that might publish the release (which should be no longer than 1 – 1.5 pages). The draft will be circulated to the sub-team for feedback once it is ready for review.

VII. SPL Process Team

The SPL Process Team (PT) is open to anyone who is interested in joining the group. The PT includes an update from the various sub-teams so it is a good opportunities to learn about other aspects of SPL that might affect OTC sub-team members (*e.g.*, electronic registration and drug listing sub-team, generics sub-team, others). Calls are every other Wednesday at 1:00 pm ET (during the same week as the OTC sub-team call) with the next call to be held on March 11th. If you are interested in joining the SPL PT, contact Marcia Howard.

VIII. Proposed Activities for the SPL OTC Sub-team

Input from SPL OTC sub-team members is needed to make the group as effective as possible. Beyond sharing notices and announcements with the group, it will not be clear how to advance projects of interest to the members without feedback. Please send any ideas, questions, or agenda topics to the sub-team leaders, Paula Markert (GSK) and Devon Morgan (Perrigo), and Marcia Howard (CHPA) whenever appropriate. If for some reason you wish to remain anonymous or there are sensitivities, you may send your message to Marcia Howard only and indicate your desire to remain private.

If there is little or no new business, we will cancel the next teleconference and share announcements, guidance documents, and *Federal Register* notices via email until a complete agenda is developed to warrant the teleconference.

IX. Upcoming SPL Educational Forums

A. FDA webinars

B. FDA face-to-face meeting on May 21, 2009, (registration is now closed due to space limitations)

Sub-team members are encouraged to share educational opportunities that might be of interest to the group.

X. Other

Virginia Hogan (Teva; Generics sub-team leader) informed members that Dun & Bradstreet should be making an announcement shortly about a program to get aid in getting DUNS numbers. Hogan also noted that the delisting process via Excel spreadsheet will continue to be accepted after the June 1, 2009, implementation date. The delisting procedure can be found below.

Finally, Hogan mentioned that Lonnie Smith (FDA) will respond to emails as quickly as he can but due to the volume of messages that he receives, he will not acknowledge receipt of the message or send interim messages to senders.

Information from the vendor OTC sub-team presentations, as well as minutes, slide presentations, and educational information, is available on the [Wiki page](#).

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Last Revised: March 10, 2009 Sent: March 10, 2009

Mass Delisting Procedures – From Generics SPL Sub-team Minutes of December 15, 2008

(please visit Wiki page for additional information)

How to mass delist prior to the date when the electronic submission of drug establishment registration and drug listing information is mandatory.

This discussion is about NDC delisting. This would be to clean up NDC lists and avoid having to submit the SPL just to have it removed.

The information the FDA needs is:

- Name of drug
- Strength & unit
- Discontinuation date (may be future dated)
- NDC Number

The above is sufficient to remove NDC numbers from the NDC database. You may put in an Excel spreadsheet with the above information and send it to: spl@fda.hhs.gov prior to June 1, 2009 [**UPDATE**: FDA will continue to accept deletions via this procedure after June 1st.]